

the foot. Taken together, these measurements may be used to determine the medial/lateral moment of the prosthetic foot.

[0061] Some embodiments of the invention integrate sensors and a microcontroller to monitor the gait dynamics of a user. For example, embodiments of the invention may be used to measure the movement and/or dynamics of a device associated with a limb, such as a prosthetic or orthotic foot. In yet other embodiments of the invention, other types of devices may be used with a foot or with other limbs. For exemplifying purposes, the following will describe an embodiment of the invention including a prosthetic foot.

[0062] One embodiment of the invention includes a prosthetic foot system that provides information relating to at least one of the following:

- [0063] 1. The number of steps taken on the foot
- [0064] 2. A toe load
- [0065] 3. A heelload
- [0066] 4. Real-time information on the foot load
- [0067] 5. An activity index (e.g., number of steps/time\*impact level)
- [0068] 6. Medial/lateral alignment of the foot
- [0069] 7. Dorsiflexion/Plantarflexion of the foot

[0070] The benefits of such data sampling include information relating to at least one of the following:

- [0071] 1. The activity of the user (e.g., from the number of steps taken in a particular period of time)
- [0072] 2. Toe load and heel load may indicate if the foot selection is correct or not. For example, the system may comprise software that processes information relating to available prosthetic foot products and determines whether the current prosthetic foot is appropriately selected for the user and/or, based on such information, suggest an alternative prosthetic foot.
- [0073] 3. Real-time load information is beneficial during alignment processes, and an integrated load indicator (e.g., integrated into the prosthetic foot) provides for dynamic alignment based on the real-time analysis.
- [0074] 4. A proprietary activity index may be used to give results on increased activity caused by different adjustments or setup configurations of various types of prostheses.
- [0075] 5. Deflection of the prosthetic foot may be, through a force model, translated over to a force value at each end of the prosthetic foot. This allows for the measurement of toe load and heel load through a single sensor unit.
- [0076] 6. From monitoring the bending of the prosthetic unit, a sudden permanent change in certain bending values may indicate a failure of the device due to breakage or delamination.

[0077] FIG. 1 depicts an example of a prosthetic foot system according to one embodiment of the invention. In general, the illustrated intelligent prosthetic foot 30 may comprise many of the common elements of a prosthetic foot, such as a heel member 32, an elongated member 34, and an attachment member 36. An intelligent prosthetic foot 30

may additionally include laminating a force sensor 38, such as a variable resistor strip, into (or onto) the prosthetic foot 30. Additionally, an intelligent prosthetic foot 30 may include a microcontroller (not illustrated), which may optionally reside on the device, such as in the housing 40 illustrated in FIG. 1. In the illustrated embodiment, connecting wires 42 provide a path for communicating data to a microcontroller (not illustrated) residing in the housing 40. The illustrated intelligent prosthetic foot 30 provides a user interface 44, consisting of two LED lights, for communicating data gathered and processed.

[0078] The force sensor 38 is advantageously positioned on the prosthetic foot so as to be able to measure forces, more particularly bending forces, on both sides of a bending axis of the foot. In one embodiment of the invention, at least one sensor is positioned lengthwise (anterior/posterior direction) on the prosthetic foot. Such positioning of the sensor(s) advantageously provides for the monitoring of portions of the prosthetic foot where maximum bending is generally expected. In a further embodiment, at least one sensor is positioned lengthwise on each side of the prosthetic foot. This provides for the sensing of differences in force in the medial/lateral plane, which may be used to calculate the moment of the foot.

[0079] When the prosthetic foot bends, the resistance in the variable resistor strip changes. A microcontroller monitors the changes in resistance (such as through continuous or periodic monitoring) and detects different bending in the foot based on the changes in resistance (e.g., such as through a predetermined algorithm). In one embodiment, the microcontroller is an ATMEL ATtinyL 5L, which may run at a frequency of 1.2 MHz. In one embodiment, the sensors and/or microcontroller may be integrated into the prosthetic foot.

[0080] In one embodiment, the interface of the system is a RS232 serial connection from the microcontroller that is connectable to any serial device over a cable or a Bluetooth connection. In other embodiments, other types of wireless technology may be used, such as infrared, WiFi®, or radio frequency (RF) technology. In other embodiments, wired technologies may be used to communicate with the microcontroller.

[0081] In one embodiment, a software program reads and interprets the data read from the prosthetic foot. A display, such as two LED's, indicates the status of the prosthetic foot system.

[0082] Calibration of the prosthetic foot system may take place when the system is reset. That is, the "normal" state of the prosthetic foot system may be defined as the state registered when the prosthetic foot system is reset. In one embodiment, the prosthetic foot system defines a range of resistive values (or "dead zone") that is associated with a relaxed, or normal, state of the prosthetic foot. Even at this relaxed state, the prosthetic foot is generally curved and may register a particular resistive value measured through the resistive strip. Resistive values that fall outside the defined range of normal state values are generally regarded as valid state changes. For example, when the user is in stride, at the heel strike state (i.e., when the heel of the user makes contact with the ground), the resistance (i.e., heel load value) measured through the resistive strip is generally less than the relaxed state value(s). At the toe load state (i.e., state just